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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,870	04/12/2001	Masad J. Damha	1770-206US FC	5859
20988	7590	06/30/2004	EXAMINER	
OGILVY RENAULT 1981 MCGILL COLLEGE AVENUE SUITE 1600 MONTREAL, QC H3A2Y3 CANADA			EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1635	
DATE MAILED: 06/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/719,870

Applicant(s)

DAMHA ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-17, 19, 20 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) 7-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6, 19, 20 and 31-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Response to Arguments*

2. Applicant's arguments with respect to claims 1, 4-6, and 18-20 under 35 USC 102(b) have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102/103*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-6, and 19-20 are rejected under 35 U.S.C. 102(b)/103(a) as being anticipated by or obvious over McCormick (US Patent No. 4,760,017).

The instant claims are drawn to a composition to selectively prevent gene transcription and expression in a sequence specific manner; which comprises an effective amount of at least one oligonucleotide selected from the group consisting of an oligonucleotide consisting of  $\beta$ -arabinose sugars hybridizing to a single stranded RNA to induce RNase H activity, and an

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oligonucleotide consisting of  $\beta$ -arabinose sugars substituted at 2' position of the sugar ring with halogen, alkyl,  $\text{CH}_2\text{F}$ ,  $\text{CF}_3$ ,  $\text{SCH}_3$ , allyl, amino, aryl, alkoxy, or azido and hybridizing to duplex DNA/DNA or DNA/RNA to form a triple helical complex, in associated with an acceptable carrier.

McCormick discloses arabinonucleic acid and the use of this polynucleotide probe in DNA or RNA hybridization assays and especially to probes containing a binding site in every constituent nucleotide (see col. 1, lines 6-12). It is noted that  $\beta$ -D-arabinonucleosides are used in the synthesis of the arabinonucleic acid probes of McCormick, see Example 1. Although, the McCormick reference does not specifically teach that the arabinonucleic probes can be used to induce RNase H activity, the probes of this reference meet all the structural limitations of Applicant's invention, particularly wherein it is drawn to an oligonucleotide consisting of  $\beta$ -arabinose sugars hybridizing to a single stranded RNA. Additionally, the hybridization solution containing the arabinonucleic acid probes described in col. 8, lines 1-18, can be considered an acceptable carrier of the oligonucleotides consisting of  $\beta$ -arabinose sugars as recited in the instant claims.

Since the prior art oligonucleotides meet all the structural limitations of the claimed oligonucleotides consisting of  $\beta$ -arabinose sugars, one of skill in the art, at the time of the instant invention, would have expected to possess the same chemical characteristics as Applicant's oligonucleotides. Therefore, the prior art oligonucleotides (i.e. an oligonucleotide consisting of  $\beta$ -arabinose sugars, capable of hybridizing to a single stranded RNA), absent evidence to the contrary, would be considered to function in the same manner as Applicant's oligonucleotides, i.e. "to induce RNase H activity." See, for example, MPEP § 2112, which states "[w]here

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applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims."

6. Claims 2-6 and 19-20, remain rejected, and claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (US Patent No. 5,646,126) in view of Chu et al. (US Patent No. 5,808,040) and Meyer, Jr. et al. (US Patent No. 5,177,196), for the reasons of record set forth in the Official Action mailed 9-25-03.

Applicant's arguments filed 4-08-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the instant claims are drawn to D-oligonucleotides comprised entirely of D-arabinonucleotide units. However, contrary to Applicant's assertions it is noted that the instant claims do not recite wherein the arabinonuceotide units are "D-nucleotide" units, the instant claims encompass oligonucleotides consisting of  $\beta$ -arabinose sugars substituted at 2' position of the sugar ring with halogen, alkyl,  $\text{CH}_2\text{F}$ ,  $\text{CF}_3$ ,  $\text{SCH}_3$ , allyl, amino, aryl, alkoxy, or azido and hybridizing to duplex DNA/DNA or DNA/RNA to form a triple helical complex, in associated with an acceptable carrier. There is no requirement that the entire oligonucleotide comprise "D-nucleotide" units.

Additionally, Applicants argue that the combination of the Cheng et al. and Chu et al. references would not have lead one of ordinary skill in the art, at the time of the instant invention, to arrive at the present invention since the oligonucleotides of Cheng et al. are not providing an activity in an “antisense” manner as it is the case in the present invention. According to applicants the molecules of Cheng et al. “can not interact with cellular RNA and form a complex.” Applicant’s assertion is not supported by evidence, absent evidence to the contrary the skilled artisan would expect that if a portion of the molecules of Cheng et al. comprised a sequence that is complementary to a target RNA sequence, these molecules would interact with cellular RNA and form a complex. The passage quoted by Applicants, on page 10 of the response filed 4-08-04 states that the modified oligonucleotides of Cheng et al. show “anticancer activity” in other than an antisense manner, however there is no evidence that antisense activity cannot be observed using the modified oligonucleotides of Cheng et al., it merely states that “anticancer activity” is not particularly associated with sequence specific binding of an oligonucleotide to its target.

### *Conclusion*

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

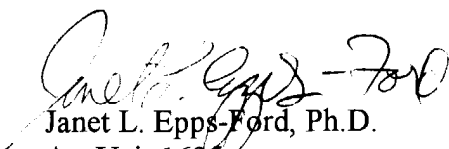
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
Janet L. Epps-Ford, Ph.D.  
Art Unit 1635  
Patent Examiner

JLE